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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,290	03/03/2004	Frank S. D'Amelio SR.	45437	3540
1609 7590 01/11/2008 ROYLANCE, ABRAMS, BERDO & GOODMAN, L.L.P. 1300 19TH STREET, N.W. SUITE 600 WASHINGTON,, DC 20036			EXAMINER ROBERTS, LEZAH	
			ART UNIT 1612	PAPER NUMBER
			MAIL DATE 01/11/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/791,290	Applicant(s) D'AMELIO ET AL.	
	Examiner Lezah W. Roberts	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 7, 9-13, 16, 17, 22 and 24-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7, 11-13, 16, 17, 22, 24, 25 and 28-33 is/are rejected.
- 7) ☒ Claim(s) 1-3, 7, 9-13, 16, 17, 22 and 24-33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the Amendment filed October 15, 2007. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Objections (New Objections)

1) Claim 9 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim recites the composition further comprises bio-saponin. This component is already disclosed in independent claim 1.

2) Claims 1-3, 7, 9-13, 16, 17, 22 and 24-33 are objected to because of the following informalities: the term "gotu" should be spelled "gota". Appropriate correction is required.

3) Claim 26 is objected to because of the following informalities: the term "are" in the phrase "each of said extracts are" should read "is". Appropriate correction is required.

4) Claim 26 is objected to because of the following informalities: the term "bioactive agent" should read "composition". Appropriate correction is required.

Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)

1) Claims 1, 5, 9 and 11 were rejected under 35 U.S.C. 103(a) as being unpatentable over Romanowski et al (US 2005/0158252). The rejection is maintained in regards to claims 1, 9 and 11.

Applicant's Arguments

Applicant argues that Applicant is only required to show as much as the reference shows when the rejection is based on obviousness. Since the Declaration demonstrates a prior invention including the claimed components, the Declaration is sufficient to overcome the rejection over Romanowski. The reference does not disclose the components of the instant claims in the recited amounts. The specific components and amounts have been found to serve particular functions and provide specific properties to the compositions. Applicant goes on to disclose what these functions are. The reference also does not disclose a holistic extract of Centipeda with a water alcohol mixture as claimed. Applicant also asserts that certain components actually enhance other components in the composition such as the enhancement of gota kola by bio-saponin. These arguments are not persuasive.

Examiner's Response

The reference discloses vitamin E (Table 1 and claim 10), therefore, Applicant is required to show vitamin E. Therefore the Declaration is insufficient. In regards to the amounts, the claims do not recite an amount for gotu kola, thyme oil, olive leaf and bio-saponin. The functions described by Applicant appear to be known functions of the disclosed materials as supported by Harrison (The Periodontal Solution: Healthy Gums Naturally), cited in the rejection below. Therefore it is *prima facie* obviousness to select a known material based on its suitability for its intended use. See *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See, e.g., *In re Linder*, 457 F.2d 506, 507 (CCPA 1972); see also *In re Dial*, 326 F.2d 430, 432 (CCPA 1964). It is suggested that Applicant recites effective amounts in regards to gotu kola, thyme oil, olive leaf and bio-saponin. The reference discloses phytoplentin, which is a holistically balanced patented herbal extract (Nature's Answer – For Your Health, page 2, PerioCleanse (2004)). In regards to the components enhancing other components, it would be beneficial for Applicant to make a showing of this enhancement by a side-by-side comparison.

2) Claims 1-3, 5-7, 9-14 and 16-33 were rejected under 35 U.S.C. 103(a) as being unpatentable over Close (US 2002/0044977) in view of Harrison (The Periodontal Solution: Healthy Gums Naturally) and Rice et al. (US 5,741,138). The rejection is

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maintained in regards to 1-3, 7, 9, 11-13, 16, 17, 22, 24, 25 and 28-33 and withdrawn in regards to claims 10, 26 and 27.

Applicant's Arguments

Applicant argues the combination of plant materials is not a random selection, but instead a combination based on experimentation to provide specific properties. The specific combination of components and the specific amounts of claim 10 results in a moisturizing feel to the mouth compared to the drying or astringent feel of many common oral rinses. The rejection is based on hindsight reasoning. The combination of cited patents and publication do not suggest the specifically claimed combination of components in the claimed amounts. There is no motivation provided for using components of Harrison and Rice in the compositions of Close.

Examiner's Response

Applicant asserts Experimental data and appears to be asserting unexpected results but does not appear to disclose a showing of these results. Applicant also does not recite the specific amounts of all the components in the instant claims. In regards to claim 26, Applicant appears to be disclosing the components of the composition and not the bioactive agent but this is not clear from the claim. The claim also recites an "effective amount", and it cannot be determined what an effective amount is. As disclosed above, it would be obvious to use components for their known function as supported by cited precedent above.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that

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any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). It has been disclosed by the prior art that the ingredients recited in the instant claims provide the functions as argued by Applicant. Furthermore, the motivation for combining of the three references is supported by the case law as cited above which discloses using known ingredients for their known functions.

Claims 1-3, 7, 11-13, 16, 17, 22, 24, 25 and 28-33 are rejected.

Claims 1-3, 7, 9-13, 16, 17, 22 and 24-33 are objected.

No claims allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lezah Roberts
Patent Examiner
Art Unit 1614


ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER